

# NIH REGIONAL SEMINAR ON PROGRAM FUNDING AND GRANTS ADMINISTRATION

May 5-7, 2004

Wyndham Miami Beach Resort, Miami Beach, FL

## Course Overview

The Office of Extramural Research (OER) sponsors semiannual NIH Regional Seminars on Program Funding and Grants. These seminars are intended to help demystify the application and review process, clarify Federal regulations and policies, and highlight current areas of special interest or concern. The seminars serve the NIH mission of providing education and training for the next generation of biomedical and behavioral scientist. NIH policy, grants management, review and program staff provide a broad array of expertise and encourage personal interaction between themselves and seminar participants. The seminars are appropriate for grants administrators, researchers new to NIH, and graduate students.

## Computer Labs - Limited Space (Additional charge)

The following computer labs will be offered in conjunction with the 2004 regional seminars.

**Note: Participants will be bused to/from computer labs. Please see schedule posted at the registration desk.**

### Hands-on eRA for Grants Managers

The Grants Management lab is geared toward the day-to-day activities of a Signing Official (SO). The session will cover NIH eRA Commons administration activities such as creating accounts, maintaining account information and viewing and updating institutional and personal profile information. Participates will learn how to run common status queries and generate hit lists. Instructors will offer "tips and hints" for effective system use and will discuss upcoming system updates.

### Hands-on eRA for Principal Investigators

The PI lab is geared toward the day-to-day activities of a Principal Investigator (PI). The lab will explore the NIH eRA Commons. Activities such as reviewing and updating personal profile information, and initiating an eSNAP (electronic simplified non-competing application progress report) will be covered. Participants will learn how to check on NIH Review Group Assignment, priority scores, summary statements, award status, and generating hit lists. Instructors will offer "tips and hints" for effective system use and will discuss upcoming system updates.

### Hands-on Financial Status Reports

The Financial Status Report (FSR) lab is geared toward those individuals that process, submit and track FSRs that are required by the NIH Office of Financial Management (OFM). This lab will cover the process of entering data, revising and submitting an electronic FSR. It will also offer resources for troubleshooting the FSR during the process.

## For further information, contact:

Division of Continuing Medical Education,  
P.O. Box 016960 (D23-3), Miami, Florida, 33101-6960  
Tel: 305/243-6716; Fax: 305/243-5613

Toll-free: 1-800-U-OF-M-CME / E-Mail: [umcme@med.miami.edu](mailto:umcme@med.miami.edu)

<http://cme.med.miami.edu>

## Accommodations

### The Wyndham Miami Beach Resort

4833 Collins Avenue  
Miami Beach, FL 33140  
Tel: 305-532-3600 ext. 2233 / Toll free: 1-800-Wyndham  
Fax: 305-532-2334 / email: [caflores@wyndham.com](mailto:caflores@wyndham.com)  
[www.wyndham.com](http://www.wyndham.com)

The **Wyndham Miami Beach Resort** is a beachside haven close to the renowned South Beach District.

Recreational amenities include access to championship golf courses, outdoor tennis courts, a beachfront health and fitness center and health spa treatments, beachfront Aqua Sports Center with a variety of water sports equipment and an outdoor heated swimming pool with poolside cabanas. The Resort is also 20 minutes from Miami International Airport and 40 minutes from Ft. Lauderdale International Airport.

Luxurious home-like guestrooms with floor-to ceiling spectacular views of the Miami skyline and South Beach are simply breathtaking.

Other amenities include a Business Center, Fitness Center, secluded outdoor swimming pool located in a lush tropical garden overlooking a magnificent white sand beach.

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## HOTEL REGISTRATION FORM May 5-7, 2004 NIH Regional Seminar on Program Funding and Grants Administration

**FAX with one night's deposit (credit card only) to:**

**Carla Flores @ 305-532-2334 or**

**Mail with one night's deposit to:**

**Atten: Reservations - UM /NIH Regional Seminar**

Wyndham Miami Beach Resort

4833 Collins Avenue

Miami Beach, Florida 33140

Name \_\_\_\_\_

Address \_\_\_\_\_

City, State \_\_\_\_\_ Zip \_\_\_\_\_

Tel(\_\_\_\_\_) \_\_\_\_\_ Fax (\_\_\_\_\_) \_\_\_\_\_

Rate Requested \$ \_\_\_\_\_ Arrival date \_\_\_\_\_ Departure date \_\_\_\_\_

**Hotel Check-in is 4:00 PM / Check-out is 11:00AM**

**Room Rates:** A limited number of rooms are available at the government rate of \$98/night. Single/Double rooms are available at \$119 + 13% tax + \$10 resort fee/day. **After April 4, 2004**, reservation requests will be considered on a space available basis; the room rate is available 3 days prior to/after event dates based on availability. Upgrades are also available upon request.

Check enclosed, payable in U.S. dollars to: **Wyndham Miami Beach Resort**

Guarantee my first night's deposit using the following credit card:

American Express®  Visa®  MasterCard®

Card Number: \_\_\_\_\_ Exp Date: \_\_\_\_\_

Name on Card: \_\_\_\_\_

Authorized Signature: \_\_\_\_\_

# NIH REGIONAL SEMINAR FACULTY

Hosted by **University of Miami**

**Florida A&M University, College of Pharmacy and Pharmaceutical Sciences**

**Carol Alderson**

Chief, Grants Policy Branch  
Office of Policy for Extramural Research Administration  
Office of Extramural Research

**Lynn M. Amende, Ph.D.**

Scientific Review Administrator  
Resources and Training Review Branch  
Division of Extramural Activities  
National Cancer Institute

**Rebecca Claycamp**

Chief Grants Management Officer  
National Institute of Mental Health

**Anthony M. Coelho, Jr., Ph.D.**

Review Policy Officer  
Office of Extramural Programs  
Office of Extramural Research

**Megan Columbus**

Regional Seminar Coordinator and  
Assistant to the Director  
Office of Policy for Extramural Research Administration  
Office of Extramural Research

**Diane Dean**

Director, Division of Grants Compliance and Oversight  
Office of Policy for Extramural Research Administration  
Office of Extramural Research

**Dennis O. Dixon, Ph.D.**

Biostatistics Research Branch  
National Institute on Allergy and Infectious Diseases

**Dolores Doherty**

Grants Management Specialist  
National Heart Lung and Blood Institute

**Joe Ellis**

Acting Director, Office of Policy for  
Extramural Research Administration  
Office of Extramural Research

**Gail Lynn Gibbons, J.D.**

Director, Division of Extramural Inventions and Technology

**Walter Goldschmidts, Ph.D.**

Acting NIH Research Training Officer  
Office of Extramural Programs  
Office of Extramural Research

**Jo Anne Goodnight**

NIH SBIR/STTR Program Coordinator  
Office of Extramural Programs  
Office of Extramural Research

**Valery M. Gordon, Ph.D., M.P.H.**

Extramural Human Subjects Research Policy Officer  
Extramural Research Integrity Liaison Officer  
Office of Extramural Programs, OER, OD

**Marcia Hahn**

Assistant Grants Policy Officer  
Office of Policy for Extramural Research Administration  
Office of Extramural Research

**Susan Kauble**

Assistant Grants Compliance Officer  
Division of Grants Compliance and Oversight  
Office of Policy for Extramural Research Administration  
Office of Extramural Research

**J.P. Kim, J.D., M.B.A., M.Sc., M.A.L.S.**

Extramural Technology Transfer Policy Specialist  
National Institutes of Health (NIH)  
Office of Technology Transfer (OTT)

**David G. Longfellow, Ph.D.**

Senior Coordinator for Carcinogenesis  
Cancer Etiology Branch, DCB  
National Cancer Institute

**Sherley Mizzell**

Procurement Analyst  
Division of Acquisition Policy and Evaluation  
Office of Acquisition Management and Policy

**Chris Pascal, J.D.**

Director  
Office of Research Integrity  
Office of the Secretary  
Department of Health and Human Services

**Michael D. Payne**

Director, Division of Financial Advisory Services  
Office of Acquisition Management and Policy

**John Salzman**

Assistant Extramural Inventions Policy Officer  
Division of Extramural Inventions and Technology Resources

**Philip F. Smith, Ph.D.**

Deputy Director  
Division of Diabetes, Endocrinology, and Metabolic Diseases  
Co-Director, Office of Obesity Research  
National Institute of Diabetes and Digestive and Kidney Diseases

**Tim Twomey**

Chief, User Support Branch  
Electronic Research Administration  
Office of Extramural Research

**Axel Wolff**

Senior Assurance Officer  
Division of Assurances  
Office of Laboratory Animal Welfare

**David Wright**

Branch Chief - Requirements Analysis Branch  
Electronic Research Administration Project

# NIH REGIONAL SEMINAR REGISTRATION

## Miami Beach, FL

**TUITION:** Tuition includes admission to sessions, continental breakfasts, refreshment breaks and course syllabus.

- |   |  |
|---|--|
| <p><input type="checkbox"/> <b>NIH Conference ** Only</b> <b>By 4/5/04</b> <b>\$250</b> <b>After 4/5/04</b> <b>\$300</b><br/>                 May 6-7, 2004<br/>                 ↓↓ Please specify below ↓↓</p> | <p><input type="checkbox"/> <b>NIH Conference ** + Computer Lab</b> <b>By 4/5/04</b> <b>\$300</b> <b>After 4/5/04</b> <b>\$375</b><br/>                 May 5-7, 2004 <b>(Pending space availability-max. of 2 labs)</b><br/>                 ↓↓ Please specify below ↓↓</p> |
|---|--|

**\*\* Please indicate which concurrent sessions you will attend.**

**Concurrent Sessions:**

**Thursday, May 6:**

**Session 1 @ 11:20 AM**

- 1a: All About Costs: A Post-Award Primer
- 1b: Current Issues at NIH
- 1c: Research Contracts
- 1d: Getting Started as a New Investigator

**Session 2 @ 2:00 PM**

- 2a: A Walk Through a Proactive Compliance Site Visit
- 2b: Electronic Research Administration
- 2c: After the Award is Made ... Then What?
- 2d: Research Integrity

**Friday, May 7:**

**Session 3 @ 8:00 AM**

- 3a: Current Issues at NIH
- 3b: All About Costs: A Post-Award Primer
- 3c: Technology Transfer: Sharing of Research Tools and Invention Reporting
- 3d: Research Training & Career Development Opportunities

**Session 4 @ 9:20 AM**

- 4a: Bumps in the Road
- 4b: Electronic Research Administration
- 4c: Iedison Invention Reporting System Demonstration

**Session 5 @ 10:50 AM**

- 5a: A Walk Through the NIH Grants Policy Statement
- 5b: Clinical Research
- 5c: Small Business Research Funding OpportuNIHTies (SBIR/STTR)
- 5d: Preaward Budget Basics

**Session 6 @ 1:00 PM**

- 6a: Common Compliance Pitfalls and Strategies for Success
- 6b: Clinical Trials
- 6c: Animal Welfare Requirements
- 6d: Open Q&A with NIH Faculty

**Session 7 @ 2:20 PM**

- 7a: Preaward Budget Basics
- 7b: Taking a Walk Through the PHS 398 Grant Application
- 7c: Conflict of Interest
- 7d: Open Q&A with NIH Faculty

- Computer Lab Only** **\$75/lab** **\$125/lab**  
 May 5, 2004 **(Pending space availability)**  
 ↓↓ Please specify below ↓↓

**Computer Labs - Please indicate lab(s):**

- \_\_\_IA: Hands-on eRA for Grants Managers (9am-12pm)
- \_\_\_IB: Hands-on eRA for Grants Managers (1pm-4pm)
- \_\_\_2A: Hands-on eRA for Principal Investigators (9am-12pm)
- \_\_\_2B: Hands-on eRA for Principal Investigators (1pm-4pm)
- \_\_\_3A: Hands-on Financial Status Reports (9am-10am)
- \_\_\_3B: Hands-on Financial Status Reports (10:30am-11:30am)

**Refunds** will be given only if written notice of cancellation is received prior to **April 5, 2004**. **A \$75 fee is charged for all refunds. After April 5, 2004, no refunds will be made.**

**Services for the Disabled:** Please contact the Division of CME prior to April 16, 2004 if you have any special needs that may require additional assistance. A conference staff member will contact you to discuss these special requirements.

**For further information please contact:**

University of Miami School of Medicine, Division of CME  
 P.O. Box 016960 (D23-3), Miami, FL 33101-6960  
 Telephone: (305) 243-6716 or 1-800-U-OF-M-CME  
 FAX: (305) 243-5613 / E-mail: [umcme@med.miami.edu](mailto:umcme@med.miami.edu)

**[www.cme.med.miami.edu](http://www.cme.med.miami.edu)**

**Mail to:** University of Miami School of Medicine  
 Division of Continuing Medical Education, (D23-3)  
 P.O. Box 016960, Miami, Florida 33101-6960  
**FAX (credit card payments only): 305-243-5613**

**How did you hear of the program?**

- |                                     |   |
|-------------------------------------|---|
| <input type="checkbox"/> Brochure   | <input type="checkbox"/> NIH Website        |
| <input type="checkbox"/> Journal Ad | <input type="checkbox"/> Flyer/Announcement |
| <input type="checkbox"/> Colleague  | <input type="checkbox"/> Other _____        |

Name (Family name and first): \_\_\_\_\_ Degree: \_\_\_\_\_

Affiliation/Organization: \_\_\_\_\_ Specialty: \_\_\_\_\_

Mailing Address: \_\_\_\_\_

City, State: \_\_\_\_\_ Zip Code: \_\_\_\_\_ Country: \_\_\_\_\_

Telephone: \_\_\_\_\_ Fax: \_\_\_\_\_

**E-mail** \_\_\_\_\_ **SSN (last 4 digits)** \_\_\_\_\_  
*(for identification purposes)*

**TUITION (please check the sessions of choice above):**

- \_\_\_ **\$250** NIH Conference Only - **Registration by 4/5/04**
- \_\_\_ **\$300** NIH Conference Only - **Registration After 4/5/04**
- \_\_\_ **\$300** NIH Conference + Computer Lab - **Registration by 4/5/04**
- \_\_\_ **\$375** NIH Conference + Computer Lab - **Registration After 4/5/04**
- \_\_\_ **\$75** Computer Lab ONLY - **Registration by 4/5/04**
- \_\_\_ **\$125** Computer Lab ONLY - **Registration After 4/5/04**

- Check enclosed payable to **UM/Division of CME** in the amount of U.S. \$ \_\_\_\_\_
  - Please charge my registration fee in the amount of \$ \_\_\_\_\_ to my:
    - Visa®
    - MasterCard®
    - Discover®
- Card Number: \_\_\_\_\_ Exp. Date: \_\_\_\_\_  
 Name on Card: \_\_\_\_\_  
 Authorized Signature: \_\_\_\_\_

# PROGRAM AGENDA

May 5-7, 2004

Wyndham Miami Beach Resort, Miami Beach, FL



## WEDNESDAY, MAY 5, 2004 - COMPUTER LABS (OPTIONAL)

7:30-8:00 AM **Registration & Continental Breakfast**

8:00 AM **Board buses to Computer Labs**

(See schedule posted at registration desk)

### Lab I: Hands-on eRA for Grants Managers

9:00-12:00PM Session A

1:00-4:00PM Session B

### Lab II: Hands-on eRA for Principal Investigators

9:00-12:00PM Session A

1:00-4:00PM Session B

### Lab III: Hands-on Financial Status Reports

9:00-10:00AM Session A

10:30-11:30AM Session B

## THURSDAY, MAY 6, 2004

7:00-8:00 AM **Registration/Continental Breakfast**

8:00-8:15 AM **Introduction of Program and Seminar Faculty**

**Norman H. Altman, V.M.D.**, Vice Provost for Research  
University of Miami

**Henry Lewis III, Pharm.D.**, Dean  
College of Pharmacy and Pharmaceutical Sciences  
Florida A&M University

**Joe Ellis**

8:15-8:40 AM **NIH Roadmap**

**Joe Ellis**

The NIH Roadmap provides a framework of NIH research priorities, identifying the most compelling opportunities in three main areas: New pathways to discovery, research teams of the future, and re-engineering the clinical research enterprise.

8:40-9:40 AM **NIH Fundamentals**

**Marcia Hahn and David Longfellow**

Starting with the basics: NIH structure, budget, roles and responsibilities, mechanisms of support. Includes fundamentals of regulations, policy and grants administration.

9:40-10:00AM **Break**

10:00-11:10AM **Scientific Peer Review**

**Anthony Coelho**

How understanding the NIH peer review process can improve your chance of getting funded.

11:20-12:30PM **CONCURRENT SESSION 1**

#### a. All About Costs: A Post-Award Primer

**Mike Payne and Diane Dean**

Overview of costing issues, including expenditure and reporting of grant funds and other important topics.

#### b. Current Issues at NIH

**Joe Ellis and Carol Alderson**

An overview of research issues, administrative and policy changes affecting NIH and its grantees. Targeted towards participants with some NIH experience.

#### c. Research Contracts

**Sherley Mizzell**

What are they? How are they awarded? Who gets them? Should you try and get one?

#### d. Getting Started as a New Investigator

**Lynn Amende and David Longfellow**

Getting it all together: finding opportunities, understanding how to convey your qualifications to reviewers, identifying appropriate mechanisms of support, utilizing the resources provided by NIH and your institution, and more.

## THURSDAY, MAY 6, 2004 (Cont'd)

12:30-2:00 PM **Lunch**

Sit with a faculty member for lunch. This is a great time to get questions answered!

2:00-3:10 PM **CONCURRENT SESSION 2**

#### a. A Walk Through a Proactive Compliance Site Visit

**Diane Dean, Mike Payne, Sherley Mizzell**

Members of the NIH Proactive Compliance Site Visit team share their approach to the site visits.

#### b. Electronic Research Administration

**David Wright and Tim Twomey**

Join us for a tour of NIH's electronic research administration systems. View the tools you can use today and learn about plans for future development.

#### c. After the Award is Made... Then What?

**Rebecca Claycamp and Phil Smith**

What happens in your institution and at the NIH between grant award and closeout. Scientific and business issues will be addressed.

#### d. Research Integrity

**Valery Gordon and Chris Pascal**

Research integrity is all of our responsibility. What is it? How do you tell if its there? What to do when its not. NIH expectations and roles are highlighted.

3:10-3:30 PM **Break**

3:30-5:00 PM **Grant Writing for Success**

**Anthony Coelho**

Insights and helpful hints on preparing an application for submission. Valuable information for anyone involved with application preparation and submission.

5:15-6:15 PM **Reception**

Take some time to relax and develop your contacts at NIH!

## FRIDAY, MAY 7, 2004

7:30-8:00 AM **Continental Breakfast**

8:00-9:10 AM **CONCURRENT SESSION 3**

#### a. Current Issues at NIH (repeated - See Concurrent 1b)

**Joe Ellis and Carol Alderson**

#### b. All About Costs: A Post-Award Primer

(repeated - See Concurrent 1a)

**Mike Payne and Diane Dean**

#### c. Technology Transfer: Sharing of Research Tools and Invention Reporting

**Gail Gibbons and JP Kim**

Policy and practice related to sharing of research tools and recommended practices for meeting Bayh Dole invention reporting requirements.

### FRIDAY, MAY 7, 2004 (Cont'd)

- 8:00-10:50 **d. Research Training & Career Development Opportunities**  
*Walter Goldschmidts and Marcia Hahn*  
 Overview of research training opportunities including: Picking the right program for each stage of your career, opportunities for women and minority institutions, etc. Implementing recommendations from the National Academy of Sciences on grad students and postdocs. The first half primarily covers policies that apply to Kirschstein-NRSA training grants and fellowships. The second half will cover policies that apply to the various career development awards. Business and administrative aspects of training grants and fellowships will be discussed. *This is a double-length session. There will be a short break.*
- 9:20-10:30 AM **CONCURRENT SESSION 4**
- a. Bumps in the Road**  
*Rebecca Claycamp and Carol Alderson*  
 How to handle less common situations: changes in PI, scope, institution; sabbaticals, etc.
- b. Electronic Research Administration**  
 (repeated - See Concurrent 2b)  
*David Wright and Tim Twomey*
- c. Edison Invention Reporting System Demonstration**  
*John Salzman*  
 Provides grantee institution technology transfer professionals with an overview of the new version of Interagency Edison.
- 10:30-10:50AM **Break**
- 10:50-12:00PM **CONCURRENT SESSION 5**
- a. A Walk Through the NIH Grants Policy Statement**  
*Carol Alderson and Rebecca Claycamp*  
 The NIH Grant Policy Statement is *the* most comprehensive document for presenting policies and regulations regarding NIH grants and cooperative agreements. A review of this document will also highlight changes in the December 2003 revision.
- b. Clinical Research**  
*Valery Gordon and Dennis Dixon*  
 Are you conducting clinical research as defined by NIH? We will answer this question and explain about the law, policy and requirements on protection and inclusions.
- c. Small Business Research Funding OpportuNIHties (SBIR/STTR)**  
*Jo Anne Goodnight*  
 Overview of the SBIR/STTR Programs, including ways industry and academia can develop mutually beneficial partnerships.
- d. Pre-Award Budget Basics**  
*Phil Smith and Joe Ellis*  
 Pointers and pitfalls of preparing budget requests from the scientific and financial/administrative perspectives.

- 12:00-1:00 PM **Lunch**
- 1:00-2:10 PM **CONCURRENT SESSION 6**
- a. Common Compliance Pitfalls and Strategies for Success**  
*Diane Dean and Susan Kauble*  
 A discussion of common compliance issues at grantee institutions, including possible causes and potential solutions.
- b. Clinical Trials**  
*Dolores Doherty and Dennis Dixon*  
 A look at the award and management of clinical trials from the NIH and applicant perspectives.
- c. Animal Welfare Requirements**  
*Axel Wolff*  
 A discussion of policy, oversight and reporting requirements on animal welfare. How to complete the grant application if use of animals is proposed at any site.
- d. Open Q&A with NIH Faculty**  
*Various NIH Staff*  
 Still have questions? Ask away at this informal question and answer session with NIH faculty.
- 2:20-3:30 PM **CONCURRENT SESSION 7**
- a. Pre-Award Budget Basics**  
 (repeated - See Concurrent 5d)  
*Joe Ellis and Phil Smith*  
 Pointers and pitfalls of preparing budget requests from the scientific and financial/administrative perspectives.
- b. Taking a Walk through the PHS 398 Grant Application**  
*Lynn Amende and Dolores Doherty*  
 Take a mentored tour through the PHS 398 grant application. Let us help you strengthen your next submission!
- c. Conflict of Interest**  
*Sherley Mizzell and Diane Dean*  
 An overview of Federal conflict of interest requirements and a discussion of the latest developments, evolving guidance, and problems institutions face when implementing the regulations.
- d. Open Q&A with NIH Faculty**  
*Various NIH Staff*  
 Still have questions? Ask away at this informal question and answer session with NIH faculty.
- 3:30-3:50 PM **Break**
- 3:50-5:00 PM **Mock Study Section Meeting**  
*Anthony Coelho and the "Never Ready for Prime Time Players"*  
 Experience the NIH peer review process in action.

**Closing Remarks**